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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,776	08/05/2003	Frederick G. St. Goar	17315-002001	1704

20985 7590 03/09/2007
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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/635,776	Applicant(s) ST. GOAR ET AL.	
	Examiner Lindsey Bachman	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,8,10-12,14-18,43 and 51-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,8,10-12,14-18,43 and 51-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9-29-03, 11-29-04, 9-21-05, 11-14-05, 6-15-06, 6-26-06, 12-26-06.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of the species that corresponds with Claim 43 (Claims 1, 8, 10, 11, 12, 14-18, 43, and 51-61) in the reply filed on 1 December 2006 is acknowledged.
2. Claims 2-7, 9, 13, 19-42, and 44-50 are cancelled from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 1 December 2006.

Information Disclosure Statement

The information disclosure statement filed 29 September 2003 is incomplete. Applicant has that there are five pages, however only page one out of five was submitted. As such, only page 1 of the IDS submitted on 29 September 2003 has been considered.

Specification

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

6. **Claims 1, 8-10, 12, and 14-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Oz, et al. (US Patent 6,269,819).**

7. Claim 1: Oz'819 discloses a device for modifying a heart valve to reduce regurgitation that includes a catheter (column 6, lines 29-34) for advancement through a patient's vasculature (column 8, lines 19-21) and a supporting structure (column 2, lines 47-54) that is adapted for deployment on the annulus (column 5, lines 36-45). The structure moves between a delivery configuration and a deployed configuration (column 6, line 61 to column 7, line 2).

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8. Claims 8 and 10: Oz'819 discloses that the supporting structure is a staple (column 6, lines 23-42 and column 5, lines 35-56).
9. Claim 12: Oz'819 discloses that the supporting structure is configured for deployment over the annulus (column 8, lines 19-30).
10. Claim 14: Oz'819 discloses that the catheter is configured to extend into the heart from a femoral venous location (column 8, lines 19-30).
11. Claim 15: Oz'819 discloses that the catheter is configured to extend across an inter-atrial septum of the heart (column 8, lines 19-30).
12. Claim 16: Oz'819 discloses that the valve is a mitral valve and the supporting structure modifies the annulus of a mitral valve (column 2, lines 20-22 and column 6, lines 61 to column 7, line 2).
13. Claim 17: Oz'819 discloses a guide catheter configured for advancement through a patient's vasculature from a remote access point into the heart (column 8, lines 19-30) and that the catheter and supporting structure are positionable through the guide catheter (column 8, lines 19-30).
14. Claim 18: Oz'819 discloses a supporting structure that is capable of tightening the annulus (column 4, lines 26-31 and Figures 24-25).

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Oz'819, as applied to Claim 1, in further view of O'Connor, et al. (US Patent, 5,450,860).

18. Oz'819 teaches the limitations of Claim 11, except for circumferentially shortening the annulus.

19. O'Connor'860 teaches that it is beneficial to circumferentially shorten the annulus with the use of supporting structures (40) because the structures can be hidden between the plicated folds that are created when the annulus is shortened. This decreases the likelihood that the structures will cause irritation or loosen. Further, shortening the annulus is known to reduce mitral regurgitation (column 8, lines 5-28). It would have been obvious to one skilled in the art at the time the invention was made to modify the device taught by Oz'819 with the device taught by O'Connor'860 because circumferentially shortening the annulus reduces mitral regurgitation and creates plications which hide the support the structure and protect it from becoming loosened.

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20. Claims 43, 51, and 53-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Northrup (US Patent 5,593,424) in further view of Oz'819.

21. Claim 43: Northrup'424 teaches a method of modifying a heart valve (column 1, lines 8-12) that includes placing anchors (10) near the annulus (Figures 2-4 and column 5, lines 17-48), coupling a filament to the anchors (column 5, line 59 to column 6, line 8) and tightening the filament to modify the annulus and reduce regurgitation (column 6, lines 3-8).

22. Northrup'424 does not teach a method of delivering the anchors.

Oz'819 teaches that it is known to delivery a device to the annulus of a heart valve via a catheter that is passed through a patient's vasculature in order to reduce mitral regurgitation (column 6, lines 28-34 and column 8, lines 19-30) because this is less invasive and poses less risk for the patient, especially if they are already weak due to their condition (column 1, line 54 to column 2, line 19). It would have been obvious to one skilled in the art at the time the invention was made to perform the method taught by Northrup'424 percutaneously, as taught by Oz'819 because it poses less risk to the health of the patient than a more invasive procedure.

23. Claim 51: Northrup'424 teaches that the anchors contain a suture (column 5, line 17 to column 6, line 8).

24. Claim 53: Northrup'424 does not teach extending the catheter into the heart from a femoral venous location.

Oz'819 teaches advancing the catheter from a femoral venous location because this is a well-known, large artery that leads to the heart and can be used to access with

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the heart with relative ease (column 8, lines 19-31). It would have been obvious to access the heart via the femoral artery as taught by Oz'819 when performing the procedure taught by Northrup'424 because this is a well-known and large artery that leads with the heart with relative ease.

25. Claim 54: Northrup'424 does not teach extending the catheter across the inter-atrial septum.

Oz'819 teaches extending the catheter across the inter-atrial septum in order to enter the left atrium of the heart. It would be obvious to one skilled in the art at the time the invention was made to pass through the inter-atrial septum, as taught by Oz'819 in order to perform the method by Northrup'424 in order to access the left atrium of the heart via a non-invasive method.

26. Claim 55, 57, 58: Northrup'424 teaches that the method can be performed on a mitral valve (column 4, lines 34-46) and tightening the filament circumferentially tightens the annulus to reduce regurgitation in the mitral valve (column 5, lines 35-48).

27. Claim 56: Northrup'424 does not teach the use of a guide catheter.

Oz'819 discloses a guide catheter configured for advancement through a patient's vasculature from a remote access point into the heart (column 8, lines 19-30) and that the catheter and supporting structure are positionable through the guide catheter (column 8, lines 19-30) because guide catheters are well-known for guiding treatment devices through a patient's vasculature and into the heart. It would have been obvious to one skilled in the art at the time the invention was made to perform the

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method taught by Northrup'424 through a guide catheter as taught by Oz'819 because they are well known for use in accessing the heart.

28. Claim 59, 60 and 61: Northrup'424 teaches that tightening the filament comprises circumferentially tightening the filament by plicating portions of the annulus (column 5, lines 16-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsey Bachman whose telephone number is 571-272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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